(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
31 December 2003 (31.12.2003)

PCT

(10) International Publication Number
WO 2004/000118 A1

(51) International Patent Classification[7]: A61B 5/15, B29C 45/14

(21) International Application Number: PCT/GB2003/002538

(22) International Filing Date: 12 June 2003 (12.06.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0214373.3 21 June 2002 (21.06.2002) GB

(71) Applicant *(for all designated States except US)*: **OWEN MUMFORD LIMITED** [GB/GB]; Brook Hill, Woodstock, Oxford OX20 ITU (GB).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **MARSHALL, Jeremy** [GB/GB]; 16 Cranham Street, Jericho, Oxford OX2 6DD (GB).

(74) Agents: **JAMES, Michael, John, Gwynne** et al.; Wynne-Jones, Laine & James, 22 Rodney Road, Cheltenham, Gloucestershire GL50 1JJ (GB).

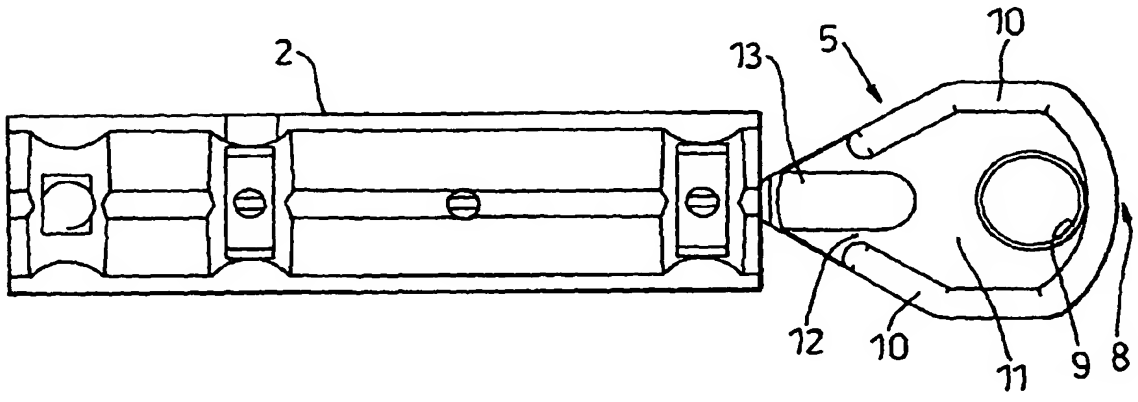
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: LANCET



(57) Abstract: Plastics material injected through an entry point of a mould at the location (8) is caused to deflect around a pin which creates the hole (9) in a guard (5), so as to increase the balance of flow of material to either side of the pin (9). In order to minimise the tendency for the plastics material to bend out of shape the tip of the needle embedded within an enlarged portion (13) the mould is formed such that the mould material is initially encouraged to divide and flow through outer thickened regions (10) surrounding a thinner portion. At point (12) the plastics material is therefore caused to slow down resulting in greater equalisation of the flow speed of the plastics material to either side of the needle tip.

WO 2004/000118 A1

LANCET

A conventional lancet comprises a needle held by a support body that has been moulded about the needle. In one form of lancet, a removable guard is moulded at the same time to cover the point of the needle. The guard can be snapped away to expose the needle for use. Conventional moulding techniques tend to subject the needle tip to a bending force so that it can be deflected to one side and thus becomes offset from the body. This can be a major disadvantage when the lancet is used in conjunction with an automatic finger pricking device, where the lancet is held by its body and the needlepoint is driven through a small hole in a support platform held against the blood-sampling site. Any misalignment of the needle could cause increased discomfort during the pricking operation. Also, recent diagnostic techniques may include a blood collecting test strip at the sampling site, so it is important to prevent any misalignment of the needle tip to avoid contact between the needle tip and the support platform, or between the needle tip and the wrong part of the test strip.

It is the object of this invention to alleviate the problem of the bending of the needle tip.

Accordingly this invention provides a lancet with a removable guard located over the point of a needle part of the lancet, the guard being formed from a moulded plastics material with an outer edge thickened region leading from the end of the guard remote from the needle point to a thinner section of the plastics material approaching the needle point.

When forming the lancet in this way, during the moulding process, the plastics material is caused to be slowed temporarily as it meets the interface between the outer edge thickened region and the thinner section approaching the needle tip. Ideally the guard will be formed with a centrally positioned hole

close to the end of the guard remote from the needle point. This hole will be created by a pin forming part of the mould for creating the guard. During the moulding process the plastics material will be caused to flow around the central pin. This helps to create a more even flow to both sides of the guard. Consequently, during manufacture, the needle tip will be subjected to controlled balanced forces which act behind the needle point, subjecting it to a lower bending force than with conventional procedures.

Ideally the plastics material forms a further thickened region about the needle tip, but separated from the outer edge region by said thinner section. This is to protect the needle tip from being accidentally being displaced through the side of the plastics material prior to use. Although the needle tip itself will be surrounded by a thickened region of material, the slowing down of the material in the thinner section will be sufficient to limit the potential for a bending force to be applied to the needle tip.

Ideally the guard will be of generally tab-like form, with the thickened region forming arc-like portions on the two side edges of the guard. The guard can be interconnected with a support body holding the needle via a breakable neck portion moulded with the guard and the support body.

The invention also extends to a method of forming a lancet in which a needle is held in a mould formed to create a support body for holding the base portion of the needle and a removable guard about the pointed needle tip, the mould having an entry point for plastics material, at the end of the guard remote from the needle point, leading to an outer edge thickened hollow region which in turn leads to a thinner hollow section approaching the needle tip and plastics material is injected into the mould via the entry point to create the guard about the needle tip.

In the preferred performance of the method the plastics material flows

around both sides of a pin located close to said entry point towards said edge thickened hollow region and ideally may flow into an enlarged hollow region surrounding the needle tip from said thinner hollow section. It is preferred that the plastics material flows from the guard through a neck portion of the mould leading to the part of the mould defining the support body.

The invention may be performed in various ways and a preferred embodiment thereof will now be described in reference to the accompanying drawings, in which:-

Figures 1 and 2 are plan, side views respectively of a lancet of this invention; and

Figure 3 is a vertical section through the lancet of Figures 1 and 2.

The lancet shown in the drawings incorporates a needle 1 (Figure 3) held within a support body 2. The tip portion 3 of the needle (having an angled point 4) is protected by a guard 5. The support body 2 and the guard 5 are moulded simultaneously about the needle 1. During moulding the needle is held by pins which create passageways 6 and 7 within the support body 1. The plastics material is injected through an entry point of the mould at the location 8 and is caused to deflect around a pin which creates the hole 9 in the guard 5, so as to increase the balance of flow of material to either side of the pin 9. Conventionally several lancets are moulded at one time to either side of a spine. The plastics material therefore enters at the location 8 at an angle and tends to bend around the far corner of the part of the mould defining the lancet such that there will be an uneven flow of pressure on to the two sides of the end portion 3 of the needle which can tend to bend it, particularly when the plastics material hits the angled face 4. There is then the possibility that the tip 3 will be bent out of shape within the guard 5 which can make the lancet more difficult to use with a finger pricker device when the guard has been removed.

In order to minimise the tendency for the plastics material to bend the tip 3 of the needle out of shape, the mould is formed such that the mould material is initially encouraged to divide and flow through outer thickened regions 10. These surround a thinner portion 11 with the thickened portion 10 terminating before it reaches the region of the needle tip 3. At this point 12 the plastics material is therefore caused to slow down resulting in greater equalisation of the flow speed of the plastics material to either side of the needle tip 3. Immediately around the needle tip 3 however the mould is formed to create a thickened region 13 to provide adequate protection for the needle tip. Although the flow of plastics material is slowed by the narrow portion 12, there is still sufficient force (although now much more evenly distributed about the needle tip 3) to push the needle back against a rear stop (which creates the hole 14) in the support body 2 to ensure that the projecting part of the needle 1 is of a required length.

In use the guard 5 is twisted to shear the material about a neck 15 so that the guard can be removed to expose the needle tip 3 for use. The moulding method employed which, in particular, creates the narrowed portion 12 between the thickened outer edge regions 10 and the thickened region 13 surrounding the needle tip 3, helps to ensure that the exposed needle tip is unlikely to be in a bent condition when the guard 5 is detached.

CLAIMS

1. A lancet with a removable guard located over the point of a needle part of the lancet, the guard being formed of a moulded plastics material with an outer edge thickened region leading from the end of the guard remote from the needle tip to a thinner section of the plastics material approaching the needle tip.

2. A lancet according to claim 1, wherein the guard is formed with a centrally positioned hole close to the end of the guard remote from the needle point.

3. A lancet according to claim 1 or claim 2, wherein the plastics material forms a further thickened region about the needle tip, but separated from the outer edge region by said thinner section.

4. A lancet according to any one of claims 1 to 3, wherein the guard is of generally tab-like form, with the thickened region forming arc-like portions on the two side edges of the guard.

5. A lancet according to any one of claims 1 to 4, wherein the guard is interconnected with a support body holding the needle via a breakable neck portion moulded with the guard and the support body.

6. A method of forming a lancet in which a needle is held in a mould formed to create a support body for holding the base portion of the needle and a removable guard about the pointed needle tip, the mould having an entry point for plastics material, at the end of the guard remote from the needle point, leading to an outer edge thickened hollow region which in turn leads to a thinner hollow section approaching the needle tip and plastics material is injected into the mould via the entry point to create the guard about the needle tip.

7. A method according to claim 6, wherein the plastics material flows around both sides of a pin located close to said entry point towards said edge thickened hollow region.

8. A method according to claim 6 or claim 7, wherein the plastics material

flows into an enlarged hollow region surrounding the needle tip from said thinner hollow section.

9. A method according to any one of claims 6 to 8, wherein the plastics material flows through a neck portion of the mould leading to the part of the mould defining the support body.

10. A lancet or a method of forming a lancet substantially as herein described with reference to the accompanying drawings.

11. Any novel combination of features of a lancet or a method of forming a lancet as described herein and/or as illustrated in the accompanying drawings.

1/1

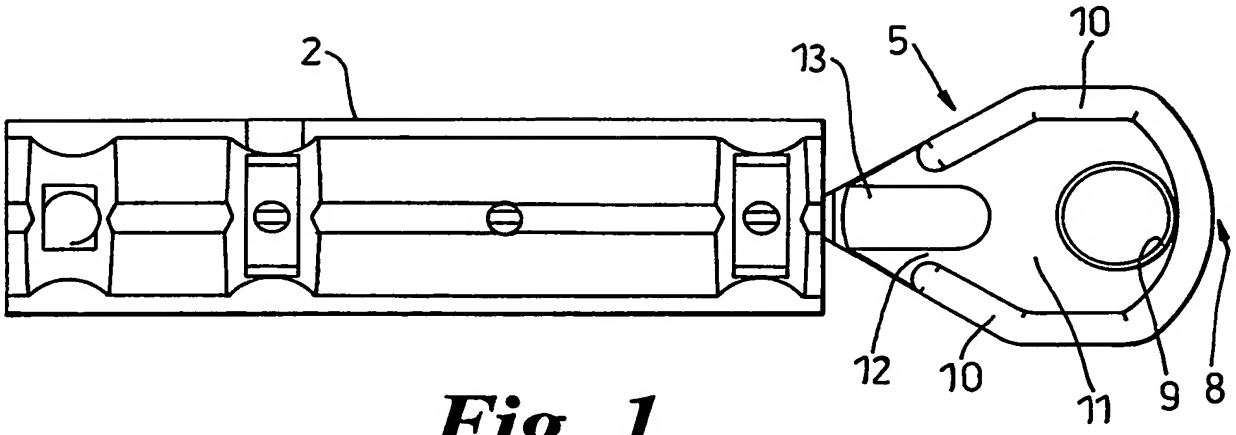


Fig. 1

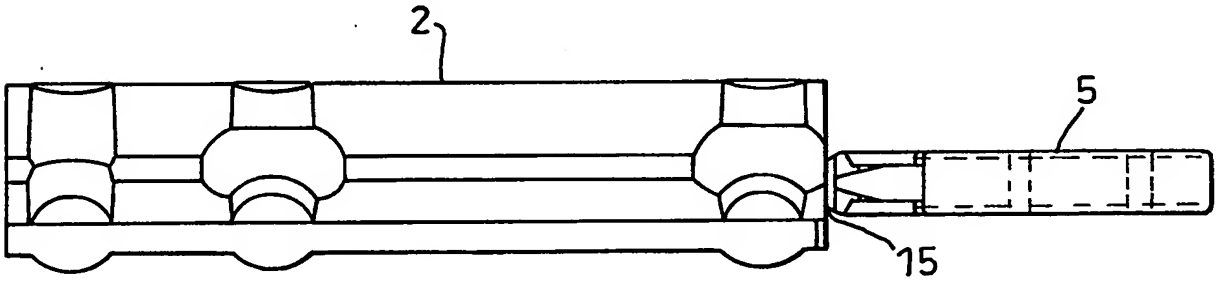


Fig. 2

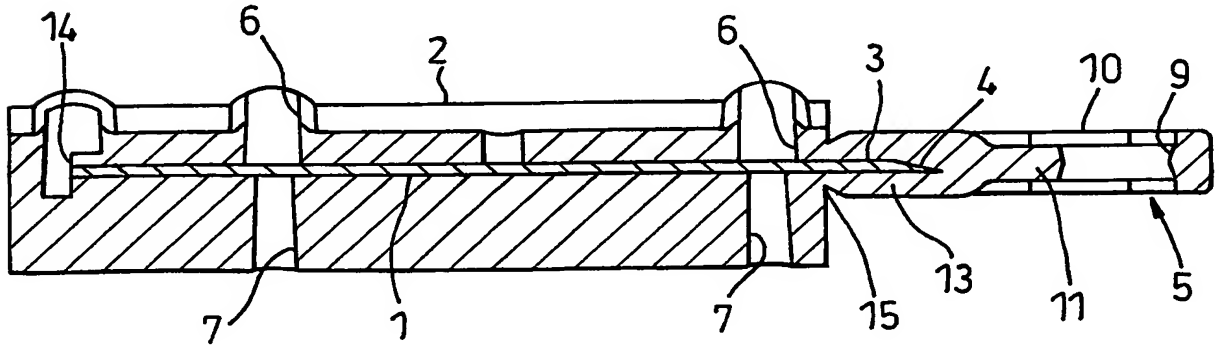


Fig. 3

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/G /02538

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/15 B29C45/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B B29C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 358 689 A (HIGGINS) 19 December 1967 (1967-12-19) the whole document	1,3,5-9
X	EP 0 589 186 A (APLS CO., LTD.) 30 March 1994 (1994-03-30) column 5, line 15-42; figures 3,4	1,2,4,5
X	GB 2 352 403 A (OWEN MUMFORD LIMITED) 31 January 2001 (2001-01-31) abstract; figures	1,2,4,5

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 September 2003	19/09/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Giménez Burgos, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/GB 03/02538

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 10,11
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/GB 03 /02538

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 10,11

The subject matter of claims 10 and 11 is defined by reference to the description and drawings which is not allowed by the PCT (see Rule 6.2 PCT). The claims do not define any clear structural features or limitations. Consequently, the scope of the claims is not clear (see Article 6 PCT) and meaningful search is not possible (see Article 17 PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
PCT/G /02538

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 3358689	A	19-12-1967	GB	1112059 A	01-05-1968
			GB	1085141 A	27-09-1967
EP 0589186	A	30-03-1994	JP	6023505 U	29-03-1994
			AU	4441493 A	03-03-1994
			CA	2104269 A1	01-03-1994
			DE	69326930 D1	09-12-1999
			DK	589186 T3	03-01-2000
			EP	0589186 A1	30-03-1994
			ES	2137212 T3	16-12-1999
			KR	137072 Y1	20-03-1999
			US	5385571 A	31-01-1995
GB 2352403	A	31-01-2001	NONE		